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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,918	09/15/2003	Scan B. Carroll	OPHD-08258	2733

7590 06/14/2004

MEDLEN & CARROLL, LLP
Suite 350
101 Howard Street
San Francisco, CA 94105

EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
662,918	CARROLL et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-4 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

Claims 1-4 are pending and under examination.

The disclosure is objected to because of the following informalities: at page 1, in the continuation data entered by the preliminary amendment of 9/15/03 applicant must update the status of application 08/810,908.

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,656,468. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims of '468 teaches all aspects of treatment within the scope of the instant claims, including use of a botulinis antitoxin, a nutritional formula, and an infant formula.

The issued claims are limited to the treatment of "enteric bacterial infectious," while the instant claims are not thus limited and would thus encompass treatment of any conditions resulting from exposure to a toxin (e.g. of bacteria, insects, jellyfish, snakes,

etc. Since the instant more generic claims encompass the subject matter of the issued more particular claims, a terminal disclaimer is required to assure that the '468 patent and any issued from the present application remain commonly owned.

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,599,539. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims of '539 teach all aspects of treatment within the scope of the instant claims.

The issued claims however, are limited to treatments of subjects intoxicated with a clostridium botulinum neurotoxin, while the instant claims are generic with respect to the type of toxin. As noted supra in the double patenting rejection over '468, a disclaimer is required to assure that the '539 patent and any issued from the present application remain commonly owned.

Claims 1 and 3-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,762,934. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims of '934 teach all aspects of treatment within the scope of the instant claims.

The issued claims are limited to treatments of subjects intoxicated with a clostridium difficile toxin, while the instant claims are generic with respect to the type of toxin. A disclaimer is required to assure that the '934 patent any issued from the present application remain commonly owned.

Claims 1 and 3-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,736,139. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims of '139 teach all aspects of treatment within the scope of the instant claims.

Issued claims are limited to treatments of subjects intoxicated with a clostridium difficile toxin, while the instant claims are generic. A disclaimer is required to assure that the '139 patent remains commonly owned with any issued from the present application.

Claims 1 and 3-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-6 and 11 of U.S. Patent No. 6,613,329. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims of '329 teach all aspects of treatment within the scope of the instant claims. Note teaching of "oral administration in claim 11; note that "enteric stability" recited in claims 4-6 would be recognized as referring to a therapeutic mixture that is administered orally.

The issued claims are limited to treatment of subjects intoxicated with a clostridium difficile toxin, while the instant claims are generic. A disclaimer is required to assure that the '329 patent remains commonly owned with any issued instantly.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-4 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Tokoro[JP 62-215534 A or US 5,080,895].

Rejection is 102(b) over JP 6221534 A and 102 (e) over US '895. For convenience, examiner will only refer to the U.S. document.

Tokoro teaches preparations of avian antibodies from the yolk of eggs. (e.g. col.6, lines 8+). He teaches that such antibodies may be raised against toxins (col.4, lines 46+) and that such antibodies may be administered orally (col.4, lines 6 and 63 and col.12, line 6). Thus all aspects of instant claim 1 are taught.

Regarding claims 3-4, note col.10, lines 20-42 teach oral administration of the yolk antibodies "as a solution in an artificial milk" to newborn piglets; as such, it is considered that "artificial milk" is within the scope of "a nutritional formula" and that, since it was administered to newborn piglets, it is within the scope of an "infant formula".

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Stolle et al (4,748, 018).

Stolle et al teach the immunization of fowl (aves) against a selected antigen. Such antigens include toxins (col.8, line 42). The immunized fowl produces antibodies

against the antigen in its eggs. These eggs can then be fed, or otherwise administered orally, to a subject. See especially col.8, line 29-col.9, line 10. Thus all aspects of claim 1 are taught.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182

Saunders/tgd

May 3, 2004